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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/755,428	01/12/2004	Roberto Pedros	2331CON2 (203-2539CON2)	9696
Covidien 60 Middletown Avenue North Haven, CT 06473	7590 07/02/2010		EXAMINER TYSON, MELANIE RUANO	
			ART UNIT 3773	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/755,428	Applicant(s) PEDROS ET AL.	
	Examiner MELANIE TYSON	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-12 and 14-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-12 and 14-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to the applicant's amendment received 19 April 2010. Claims 1-9 and 13 are cancelled. New claim 35 has been added. The amendments made to the claims do not place the application in condition for allowance for the reasons set forth below.

Response to Arguments

Examiner agrees with the applicant that the amendments made to the specification and claims overcome the previous objections made to the drawings and specification and overcome the previous 112 rejection. The corrections have been accepted.

Examiner agrees with the applicant that Kuehn fails to disclose tissue engaging members movable between the jaw members as now required by amended claim 10. A new rejection necessitated by amendment is set forth below.

Examiner agrees with the applicant that neither Kuehn nor Harrison disclose an elongated shaft including recesses adjacent the distal end such that attachment members included on the jaw members are positionable within the recesses as now required by amended claim 29. A new rejection necessitated by amendment is set forth below.

Applicant's argument that neither Kuehn nor Harrison disclose an elongated shaft having a lumen being configured and dimensioned to receive a guidewire as now required by amended claim 25 and new claim 35 has been fully considered but is not persuasive. Harrison discloses an elongated shaft 80 having a lumen 70 that forms a

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passageway sized to permit the introduction of "at least" a manipulator, thus is considered to be configured and dimensioned to receive a guidewire if so desired (see new rejection necessitated by amendment below).

The applicant has noted a terminal disclaimer will be executed upon the indication that the claims are allowable. Therefore, the obviousness-type double patenting rejections of the claims will be maintained until the proper terminal disclaimer has been executed.

Claim Objections

Claim 29 is objected to because of the following informalities: a typographical error. In line 21, replace "that" with --the-- such that the line reads "the attachment members being further configured...". Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 10-12 and 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harrison et al. (U.S. Patent No. 5,403,326) and Kuehn et al. (U.S. Patent No. 6,165,183).

Harrison discloses an apparatus capable of substantially closing a vascular opening (see entire document) comprising a housing (82) having proximal and distal ends and a longitudinal axis (for example, see Figure 9), an elongated shaft (80), one (hook 40) or two tissue engaging members (each jaw of manipulator 72 may be considered a tissue engaging member) disposed adjacent the distal end of the housing (the elongate portion of the manipulator that carries the jaws is considered to be disposed adjacent the housing) and being longitudinally and reciprocally movable relative to the housing to engage tissue (the manipulator is slidably disposed in lumen 70), two jaw members (each jaw of 68) positioned adjacent the tissue engaging members and being movable independently thereof that close thus are capable of seizing vascular tissue, a deployment member (84) connected to the tissue engaging members such that the engaging members move relative to the housing and between the jaw members to facilitate engagement with vascular tissue, and an actuator (88) for closing the jaws, wherein the tissue engaging members are capable of being retracted into the housing such that they are entirely concealed within the housing (72 is separate and slidable thus may be introduced into and/or retracted along any point of 68).

Harrison fails to disclose the one or two tissue engaging members comprise two hooks or J-shaped configurations disposed in general diametrical opposed relation in the advanced position, wherein the engaging members are composed of a shape memory

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material such that they are adapted to resume the hook or J-shaped configuration when unstressed.

Kuehn discloses an apparatus capable of substantially closing a vascular opening (see entire document) comprising a housing (126) and at least two tissue engaging members (470, 472) being adjacent the distal end of the housing (for example, see Figure 22) and being longitudinally, reciprocally, and radially outwardly movable relative to the housing to engage tissue to assist in applying a fastener thereto (for example, see column 10, lines 4-14), each having a distal segment (480, 482) arranged in a general hook or J-shaped configuration being disposed in general diametrical opposed relation and generally curving away from the longitudinal axis when in an advanced position (for example, see Figure 22), wherein the engaging members have sharpened ends (for example, see column 10, lines 4-14). One having ordinary skill in the art would recognize that the Harrison's device may be utilized to fasten tissue other than tissue at the GEJ, and Harrison further discloses "at least one hook" indicating that more than one tissue engaging member in a general hook or J-shaped configuration may be utilized. The substitution of one known element (Kuehn's tissue engaging members) for another (Harrison's tissue engaging single hook or two engaging members) would have been obvious to one of ordinary skill in the art at the time of the invention since the substitution of the tissue engaging members would have yielded predictable results, namely, providing a means for effectively engaging tissue.

With further respect to claims 11 and 12, shape memory materials are well known in the art. It would have been obvious to one having ordinary skill in the art at the

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time the invention was made to form Harrison's, as modified by Kuehn, tissue engaging members of a shape memory material such that they have a hook or J-shape configuration when unstressed, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of design choice.

With further respect to claim 20, Harrison as modified by Kuehn fails to disclose specifically a spring mechanism for biasing the jaw members towards the closed position, although Harrison discloses the jaws are biased open and thus the device has some sort of biasing mechanism. It is well known in the art to use spring members with actuators, for example, clip appliers, in order to bias the jaws of the device into either an open position or a closed position. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided Harrison's device, as modified by Kuehn, with a spring member to bias the jaw members. Furthermore, to provide the spring such that the jaws are biased closed (as opposed to biased open as disclosed by Harrison) would have been obvious to one having ordinary skill in the art at the time the invention was made, since such a modification would still result in a simplified device requiring only a single input from the user to the actuator to open and close (or operate) the jaws.

Claims 14-18, 24-28, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harrison et al. (U.S. Patent No. 5,403,326), Kuehn et al. (U.S. Patent No. 6,165,183), and Sutton et al. (U.S. Patent No. 5,762,613).

Harrison and Kuehn disclose the claimed invention (see rejection above for similar limitations recited in claims 25-28) except for the elongated shaft (80, having a lumen 70) being at least partially disposed in the housing (82). Sutton discloses an apparatus comprising a housing (for example, see Figure 1) and an elongate shaft (24). Sutton teaches the elongated shaft is at least partially disposed in the housing (for example, see Figure 1). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Harrison's elongated shaft at least partially disposed in the housing as taught by Sutton. Doing so would yield a strong connection between the two thus reducing the risk of breaking or detachment between the two during use.

With further respect to claim 15, the lumen (70) of Harrison's elongated shaft is considered a longitudinal slot for accommodating the tissue engaging members.

With further respect to claim 16, Harrison's jaw members include an attachment member (90) to adjoin tissue.

With further respect to claims 17 and 18, fasteners formed of biocompatible metal materials, which are conductive, are well known in the art. It would have been obvious to one having ordinary skill in the art at the time the invention was made to form Harrison's attachment member of a conductive biocompatible metal, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of design choice.

With further respect to claim 24, the attachment member has surfaces that are capable of being received by a recess formed on the elongated shaft (it is noted that the recess is not positively recited in claim 24).

With further respect to claims 25 and 35, Harrison discloses the elongated shaft is sized to permit introduction of "at least" a manipulator, thus is considered configured and dimensioned to also receive a pre-positioned guidewire if so desired.

Claims 29, 30, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sutton et al. (U.S. Patent No. 5,762,613) and Fain et al. (U.S. Patent No. 5,290,299).

Sutton discloses an apparatus (see entire document) capable of substantially closing a vascular opening comprising a housing having proximal and distal ends and a longitudinal axis (for example, see Figure 1), an elongated shaft (14) at least partially positioned within the housing having a lumen configured and dimensioned to receive a guidewire (50) and having recesses formed adjacent the distal end (slot 70 forms a top recess and a bottom recess), and two jaw members (80, 81) that close thus are capable of seizing vascular tissue, wherein the jaw members include attachment members (40, 41) capable of engaging tissue extending from the jaws thus are "configured and dimensioned to adjoin tissue adjacent a vascular opening" as claimed, and wherein the attachment members are configured and dimensioned for receipt by the recesses in the elongated shaft (for example, see Figure 4). Harrison fails to disclose tissue engaging members.

Fain discloses an apparatus (see entire document) capable of substantially closing a vascular opening comprising a housing and jaw members (for example, see Figure 5E). Fain teaches further providing the device with tissue engaging members (44) adjacent the jaw members and the distal end of the housing, wherein the tissue engaging members are longitudinally movable independent of the jaw members. It would have been obvious to one having ordinary skill in the art at the time the invention was made to further provide Sutton's device with tissue engaging members as taught by Fain. Doing so would assist in positioning and holding the selected tissue as the jaw members are utilized, thus enabling the jaw members to be repeatedly opened and closed if so required to effectively accomplish the intended result.

Claims 31, 33, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sutton et al. and Fain et al. as applied to claim 29 above, and further in view of Kuehn et al. Sutton as modified by Fain fails to disclose the two tissue engaging members comprise two hooks or a J-shaped configuration disposed in general diametrical opposed relation in the advanced position, wherein the engaging members are composed of a shape memory material.

Kuehn discloses an apparatus capable of substantially closing a vascular opening (see entire document) comprising a housing (126) and at least two tissue engaging members (470, 472) being adjacent the distal end of the housing (for example, see Figure 22) and being longitudinally, reciprocally, and radially outwardly movable relative to the housing to engage tissue to assist in applying a fastener thereto (for example, see column 10, lines 4-14), each having a distal segment (480, 482)

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arranged in a general hook or J-shaped configuration being disposed in general diametrical opposed relation and generally curving away from the longitudinal axis when in an advanced position (for example, see Figure 22). The substitution of one known element (Kuehn's tissue engaging members) for another (the tissue engaging members of Sutton as modified by Fain) would have been obvious to one of ordinary skill in the art at the time of the invention since the substitution of the tissue engaging members would have yielded predictable results, namely, providing a means for effectively engaging tissue. With further respect to claim 31, shape memory materials are well known in the art. It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the tissue engaging members of a shape memory material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of design choice.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

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be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 10-12 and 14-35 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,248,124.

Although the conflicting claims are not identical, they are not patentably distinct from each other because some of the claims of the patent "anticipate" some of the claims of the application and some of the application claims would have been obvious over the patent claims. Both inventions require a housing, tissue engaging members [tissue everting members; note that the everting members inherently have a deployment member in order to perform the recited deploying function] that move between jaw members [jaw members disposed about the everting members], wherein the jaw members move between open and closed positions, an elongated shaft having recesses [camming surface], and a conductive attachment member [electrode; note: in which the inwardly extending attachment as recited in the application claims forms a cooperating "camming surface" as recited in the patent claims]. Accordingly, the application claims are not patentably distinct from the patent claims. Here, the more specific patent claims (i.e., specifically requiring the attachment be an "electrode" for closing the opening) encompass the broader application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may

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not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

With further respect to claim 20, it is well known in the art to use spring members with actuators, for example, clip applicators, in order to bias the jaws of the device into either an open position or a closed position. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided the '124 invention with a spring member to bias the jaw members closed. Doing so would yield a simplified device requiring only a single input from the user to the actuator to open and close (or operate) the jaws.

With further respect to claims 29 and 35, providing medical devices with lumens or slots for tracking over a guidewire is well known in order to minimize damage to healthy tissue while inserting the device and tracking the device to the proper position within the body. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the elongated shaft of the '124 invention with a guidewire lumen or slot in order to be able to track the device over a properly positioned guidewire within the body, thus facilitating proper placement within the body while reducing the risk of damaging healthy tissue.

Claims 10-12 and 14-35 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 6,676,685 B2.

Although the conflicting claims are not identical, they are not patentably distinct from each other because some of the claims of the patent "anticipate" some of the

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claims of the application and some of the application claims would have been obvious over the patent claims. Both inventions require a housing, tissue engaging members having a deployment member and move between jaw members [jaw members disposed about the everting members], wherein the jaw members move between open and closed positions, an elongated shaft having recesses [camming surface], and a conductive attachment member [thermal transmitting portion or electrode; note: in which the inwardly extending attachment as recited in the application claims forms a cooperating "camming surface" as recited in the patent claims]. Accordingly, the application claims are not patentably distinct from the patent claims. Here, the more specific patent claims (i.e., specifically requiring the attachment be a "thermal transmitting portion" or an "electrode" for closing the opening) encompass the broader application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

With further respect to claim 20, it is well known in the art to use spring members with actuators, for example, clip appliers, in order to bias the jaws of the device into either an open position or a closed position. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided the '685 invention with a spring member to bias the jaw members closed. Doing so

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would yield a simplified device requiring only a single input from the user to the actuator to open and close (or operate) the jaws.

With further respect to claims 29 and 35, providing medical devices with lumens for tracking over a guidewire is well known in order to minimize damage to healthy tissue while inserting the device and tracking the device to the proper position within the body. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the elongated shaft of the '685 invention with a guidewire lumen in order to be able to track the device over a properly positioned guidewire within the body, thus facilitating proper placement within the body while reducing the risk of damaging healthy tissue.

Claims 10-12 and 14-35 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 7,252,666 B2.

Although the conflicting claims are not identical, they are not patentably distinct from each other because some of the claims of the patent "anticipate" some of the claims of the application and some of the application claims would have been obvious over the patent claims. Both inventions require a housing, tissue engaging members [tissue everting members; note that the everting members inherently have a deployment member in order to perform the recited deploying function], jaw members that move between open and closed positions, an elongated shaft having recesses [camming surface], and a conductive attachment member [electrode; note: in which the inwardly extending attachment as recited in the application claims forms a cooperating "camming

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surface" as recited in the patent claims]. Accordingly, the application claims are not patentably distinct from the patent claims. Here, the more specific patent claims (i.e., specifically requiring the attachment be an "electrode" for closing the opening) encompass the broader application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

With further respect to claim 20, it is well known in the art to use spring members with actuators, for example, clip appliers, in order to bias the jaws of the device into either an open position or a closed position. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided the '666 invention with a spring member to bias the jaw members closed. Doing so would yield a simplified device requiring only a single input from the user to the actuator to open and close (or operate) the jaws.

With further respect to claims 29 and 35, providing medical devices with lumens or slots for tracking over a guidewire is well known in order to minimize damage to healthy tissue while inserting the device and tracking the device to the proper position within the body. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the elongated shaft of the '666 invention with a guidewire lumen or slot in order to be able to track the device over a

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properly positioned guidewire within the body, thus facilitating proper placement within the body while reducing the risk of damaging healthy tissue.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE TYSON whose e-mail is Melanie.tyson@uspto.gov and telephone number is (571) 272-9062. The examiner can normally be reached on Monday through Thursday 10-8 (max flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie Tyson/
Examiner, Art Unit 3773
June 29, 2010